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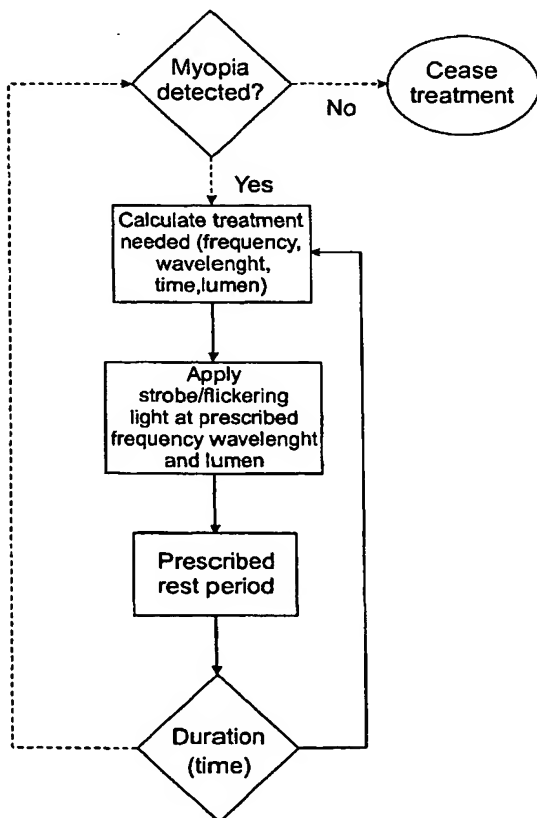
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[Continued on next page]

(54) Title: A METHOD OR APPARATUS FOR INHIBITING MYOPIA DEVELOPMENT IN HUMANS



(57) Abstract: A method of inhibiting myopia by exposing a person to a strobing or flickering light or pattern at a prescribed frequency and having a prescribed wavelength for a prescribed period.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

A METHOD OR APPARATUS FOR INHIBITING MYOPIA DEVELOPMENT IN HUMANS

FIELD OF THE INVENTION

5 This invention relates to a method and apparatus for inhibiting the development of myopia in humans.

BACKGROUND OF THE INVENTION

10 Myopia is a refractive eye disorder that affects a large segment of the population (30% in Australia, up to 90% in Asia). In particular it is characterised by a normal ability to see nearby objects but a reduced ability to see objects at a far distance. Thus the colloquial term for this condition is nearsightedness or shortsightedness.

15 This condition can have an onset either during childhood, especially from the ages of 6 to 14 years, or young adulthood (15 to 25 years) and typically worsens, particularly as a person grows through adulthood. The person's vision becomes increasingly blurry when focusing on distant objects, requiring increasingly stronger optical correction over time.

20 There are various anatomical explanations for the presence of myopia. These include the eyeball developing with a greater than normal length, possibly due to developing an enlarged vitreous chamber, alternately the cornea or the lens may be too strongly powered. The most common cause is a longer than normal eye.

These developments result in the eye not needing to accommodate to focus on near objects and create a blurry image on the retina when focusing on more distant objects. Further it is suggested that both genetic and environmental factors are important in myopia development with prolonged near work being associated with myopia.

Animal models have shown that abnormal visual experience can lead to myopia. For example, translucent diffusers placed over the eyes of animals causes them to develop myopia.

In "Experimental Myopia in Cats Reared in Strobic Illumination" (Cremieux, Orban, Duysen, Amblard and Kennedy), experiments on cats have shown that myopia can be induced by subjecting kittens to low frequency strobing lights (~2Hz) for more than 4 hours per day. This suggests that test subject animals can be prepared for myopia studies by exposing young animals to low frequency strobic illumination while they are developing their vision.

A popular way to compensate for myopia is to use concave lenses, for example in eyeglasses or contact lenses. The concave lens shifts the image plane to be coincident with the retina and thus brings the distant objects into clearer focus. A problem with these lenses is that they do not stop the myopia from developing and as the eye continues to elongate, stronger and stronger lenses are required and vision gradually worsens.

Another form of correcting myopia is to operate on the cornea using refractive laser surgery techniques. This remedy is expensive and the long

term effects are not yet known. Furthermore this treatment is only available to adults with stabilised myopic eyes and further operations may be required if the refractive error changes in the future. Surgical correction of the myopia can also result in a slight reduction in best vision and does not treat the

5 cause of the myopia (ie. an elongated eye).

Another costly remedy is for the myopic individual to take drugs and eye drops (for example pirenzepine) to combat the myopia. There are not currently any drops that are known to effectively inhibit myopia development. Once again, the long term effects of these remedies are unknown and it is a

10 costly solution to the problem involving continual prescriptions and health risks. Further, the eye drops may include side effects of dilating the pupil and reducing the focusing ability of the patient.

There is a need for a low cost, non-invasive treatment that assists in the retardation or inhibition of the development of myopia, especially one that

15 is safe for use on children during the onset of myopia.

OBJECT OF THE INVENTION

It is an object of the invention to overcome or alleviate one or more of the above problems or to provide the consumer with a useful commercial

20 choice.

DISCLOSURE OF THE INVENTION

In one form, although it need not be the only or indeed the broadest

form, the invention resides in a method of inhibiting myopia development in a human subject including the steps of:

prescribing a frequency and exposure time of a strobing or flickering light or pattern to reduce the rate of myopia development for the subject;

5 treating the subject with a strobing or flickering light or pattern at the prescribed frequency and exposure time.

Preferably the treatment is repeated as required, such as daily.

Preferably, the method also includes the step of measuring the myopia of the subject.

10 By 'inhibiting' it is meant that the treatment reduces the advance of existing myopia and may prevent development of myopia if treated before onset.

In another form, the invention resides in a method of inhibiting myopia development in human subjects including the step of:

15 exposing the eyes of a subject to light flashing at a frequency in the range of 1 to 60 Hz for at least ten minutes per treatment.

Preferably the treatment occurs each day or each alternate day.

Preferably, the method includes a feedback loop for adjusting the treatment in response to the effectiveness of the treatment in terms of
20 measured progress of the subject.

Preferably, the treatment is applied during daylight hours.

The treatment will preferably involve visible light (excluding ultraviolet and infrared) and may exclude short wavelengths (blue light).

In another form, the invention resides in an apparatus for inhibiting myopia developments in human subjects comprising:

a strobable light;

a means of adjusting a frequency at which the light strobes;

5 a means of adjusting a period of time over which the light strobes; and
wherein said light strobes at a desired frequency for a desired time period.

The apparatus may further comprise a feedback means of measuring myopia and making an adjustment to the period of time and the frequency
10 the light strobes in response to the measured myopia.

Suitably, the apparatus operates at a frequency in the range 1 to 60 Hz.

Most preferably, the frequency used is in the range 5 to 20 Hz.

Generally the frequency used will compensate for the frequency of the
15 background lighting.

Suitably, the time period will last for at least five minutes each day, or preferably ten or twenty minutes each day.

Most preferably the treatment will be applied for 5 or 10 minute periods every hour over a 2 to 10 hour period.

20 Generally the intensity of the light used will compensate for the intensity of the background lighting.

Most preferably, the wavelength of the light will be about 550 nm.

Suitably the wavelength of light will be selected to compensate for the

wavelength of the background light.

Preferably, the apparatus may further include a base.

Preferably the base will be in the form of eyeglass frames with the light located near the hinge.

5 In another form the base will be mountable to a table.

The base may be in the form of a lamp stand.

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments of the invention will now be described with reference to
10 the accompanying drawings in which:

FIG. 1 shows a flow diagram of the steps involved in the invention;

FIG. 2 shows a diagram of the invention mounted to a eyeglass base;

FIG. 3 shows a diagram of the invention mounted to a lamp stand
base.

15

DETAILED DESCRIPTION OF THE DRAWINGS

The first step in treating myopia is to assess the subject for their current condition. There are various means for testing myopia including using an ophthalmoscope, refractometer, infrared retinoscopy, A-scan
20 ultrasound, or flicker ERG, to test the reflection from the retina, with myopia being diagnosed when the subject's refraction is measured to be negative (typically in the range of 0D to -10D), with more negative values representing more severe myopia. Once the subject is identified as myopic, the extent of

myopia can be assessed to determine the best treatment.

Once the extent of myopia is known, the next step is to determine a specific treatment for the subject. In particular, specific frequency ranges and durations for treatment will target the particular myopia. The optimal
5 frequency may vary and faster progression rates may require higher frequencies and longer duration of treatment.

Flicker ERG may be utilised to determine the optimal flicker frequency and/or stimulus pattern. Subjective responses of flicker perception and/or the critical fusion frequency may also be utilised.

10 Factors such as background lighting frequency, background lighting wavelength and background lighting intensity may be compensated by the strobe light for the best results. For example, if background lighting is incandescent it has little 50Hz flicker and provides light with a wavelength in the yellow range around 600 nm, while fluorescent lighting may have 100Hz
15 flicker and much higher colour temperatures, in the blue region of the spectrum.

White light stimulates the maximum number of cone photoreceptors in the eye, as it activates the long, mid and short wavelengths. Hence the method or apparatus will be most effective for stimulating improved vision
20 when the subject is exposed to white light. Thus when the background lighting is blue, as in halogen lighting, the applied lighting must compensate for the lack of red and green wavelengths. Alternatively, when the background lighting is yellow, as in incandescent lighting, the compensating

light must be more in the blue/green bandwidth range.

Intensity of the background lighting will also need to be considered when prescribing a strobe light. The optimal intensity for treatment is 1000 to 1300 lumen. Thus if the background lighting is dimmer than this, the treatment may not be as effective as the strobing light will be distracting and visually disturbing. When the background lighting is at the high end of this intensity range, the strobe light can be brightened to complement it.

Additionally the frequency of the strobe light will need to be calculated to compensate for the background lighting frequency, for example, the 50 Hz of halogen lighting or the lack of flicker in incandescent lighting. A typical frequency for the device would be within the range 5 to 20HZ, but it would be possible to use frequencies between 1 to 60Hz to the same effect. The impact of strobe lighting on subjects would need to be considered before prescribing the treatment, as it is understood epilepsy can be triggered by certain frequencies and thus the treatment may be of lesser use for a subject with epileptic tendencies.

After characterising the myopia and calculating the treatment parameters, the next step is to prescribe a device for the subject to use for treatment. For example a light emitting diode (LED) could be positioned on a base worn on the subject's head during reading. The diode would emit light at a particular wavelength, with a programmed frequency, programmed illumination/dimness and programmed duration determined specifically for the subject.

The light emitting diode device would include means for adjusting the frequency, illumination and duration of treatment as required for the subject. The diodes are replaceable to provide for different wavelengths of light for treatment as required.

5 Current microprocessor technology allows the production of small, application specific integrated circuits which would be suitable for providing the required control of wavelength, intensity, pulse frequency and pulse duration.

10 Another embodiment would be to use a strobe light on a base to emit the light for treatment. Once again, this lamp would need to include a means for adjusting the frequency, illumination and duration of the light to be used for treating subjects.

15 The base as illustrated in FIG. 2 and FIG. 3 could comprise a portable structure such as spectacle frames (20) or other head attachments to allow the light, such as a LED (21), to be positioned close to the eye and controlled by a microprocessor (22). Additionally the base could be a more solid structure, such as a lamp base (30), formed to rest on a desk or table during use. In this form the light source would be a strobe lamp (31) supported on the base (30) and having a control to adjust the frequency (33), on/off toggle switch (34) and an adjustable timer (35).

20

The optimal delivery of the strobe treatment would be for 10 minutes per hour throughout the day. In practical application, it may also be provided in a single duration once per day. For children at school, an effective

treatment would be during an hour of reading after school.

Although the preferred treatment delivery modality is a strobing light as described above, other temporally modulated flickering targets may be effective. For instance, the strobing light may be replaced by a flickering
5 pattern on a screen, such as a computer monitor or small hand-held display. In this embodiment the pattern is made up of a grid of lines, squares, or other shapes. The pattern has areas of low luminance (black) and high luminance (white) which alternate at a predetermined frequency. This delivery method may be more suitable for older children who spend a significant amount of
10 time looking at a computer screen. The effect is essentially the same as the strobing light but is delivered directly from the viewing area. The treatment may be delivered from a small section of the screen while other programs are running or may be part of a separate treatment program that runs at predetermined times.

15 Similarly, the treatment may be delivered from a television screen while watching television programs. In this embodiment a small set-top box delivers a television frequency signal in-line with the received television signal. The set-top box is programmed to provide a 'test pattern' type signal in one corner of the screen. As with the strobing light embodiment the 'test
20 pattern' flickers at a pre-determined frequency for a pre-determined period of time.

The final step in the iterative process is a feedback loop, where myopia is remeasured and treatment is recalculated. The success of the

treatment will be measurable as a reduction in the myopia of the subject. As the myopia reduces the treatment required will need to be adjusted with frequencies reduced and duration decreased. This would be achieved by adjusting the frequency and the duration.

5 A professional with the measurement methods described for diagnosing the myopia can perform the measurement of the myopia, at a *designated time after treatments*. Additionally a feedback mechanism can be included with the device, which automatically adjusts the treatment. Once the reduced myopia is measured, a new program of treatment will be
10 calculated considering new frequency and new duration required.

A feedback mechanism for automatically adjusting the treatment would measure the electrical signals from the retinal output and calculate the new required parameters, or a subjective psychophysical equivalent could be used.

15 Treatment of subjects is measured as a reduction in the rate of growth of myopia with an expected reduction of 50%. This treatment is an iterative process with the measurements providing a feedback mechanism so the treatment can be controlled as required. At a predetermined point of measured myopia progression, such as -0.25 D, treatment may no longer be
20 needed and the subject should be monitored for future regression in vision.

Recent scientific experiments on animals have suggested that exposing the eyes of test subjects to flashing lights at a certain frequencies can cause myopia to develop. This has been useful in providing animal

subjects with myopia so that various remedies can be tested on them. This research is in conflict with the invention herein described, as flashing lights are being used to treat existing myopia rather than cause it.

As domestic lighting is commercially available in specific packaged
5 forms, specific compensating lights can be prepared for use with lighting available in the market. For example if the background light is an incandescent 100W globe, the compensating frequency, wavelength and luminosity can be predetermined.

It should be appreciated that various other changes and modifications
10 may be made to the embodiments described without departing from the spirit or scope of the invention.

CLAIMS

1. A method of inhibiting myopia development in a human subject including the steps of:
 - prescribing a frequency and exposure time of a strobing or flickering
 - 5 light or pattern to reduce the rate of myopia development for the subject; and
 - treating the subject with a strobing or flickering light or pattern at the prescribed frequency and exposure time.
2. The method of claim 1 wherein the step of treating occurs each day or each alternate day.
- 10 3. The method of claim 1 further including the step of measuring the myopia of the subject.
4. A method of inhibiting myopia development in human subjects including the step of:
 - exposing the eyes of a person to light flashing at a frequency in the
 - 15 range of 1 to 60 Hz for a selected period.
5. The method of claim 4 wherein the step of exposing occurs each day or each alternate day.
6. The method of claim 4 further including the step of selecting the wavelength of the light, the intensity of the light, the frequency of flashing and
- 20 the duration of flashing.
7. The method of claim 4 further including the step of recording feedback and using a feedback loop to adjust the treatment response to the effectiveness of the treatment in terms of measured progress of the subject.

8. The method of claim 4 wherein the light flashes at a frequency in the range between 5 and 20 Hz.
9. The method of claim 4 wherein the step of exposing is applied for at least 5 minute periods every hour over a 2 to 10 hour period.
- 5 10. The method of claim 4 wherein the step of exposing is applied for 10 minute periods every hour over a 2 to 10 hour period.
11. The method of claim 4 wherein the step of exposing is applied for at least 20 minute periods every hour over a 2 to 10 hour period.
12. The method of claim 4 wherein the step of exposing is applied during
10 daylight hours.
13. The method of claim 4 wherein the light is visible light.
14. An apparatus for inhibiting myopia development in humans comprising:
a strobable light;
15 a means of adjusting a frequency at which the light strobes;
a means of adjusting a period of time over which the light strobes;
wherein said light strobes at a desired frequency for a desired time period.
15. The apparatus of claim 14 further comprising:
20 a feedback means of measuring myopia and making an adjustment to the period of time and the frequency the light strobes in response to the measured myopia.
16. The apparatus of claim 14 wherein the light is in the visible range.

17. The apparatus of claim 14 further comprising means for adjusting a wavelength of said strobable light.
18. The apparatus of claim 17 wherein the wavelength of the light is about 550 nm.
- 5 19. The apparatus of claim 14 wherein the strobable light operates at a frequency in the range 1 to 60 Hz.
20. The apparatus of claim 14 wherein the strobable light operates at a frequency in the range 5 to 20 Hz.
21. The apparatus of claim 14 wherein the frequency of the strobable light
10 compensates for the frequency of the background lighting.
22. The apparatus of claim 14 wherein the intensity of the strobable light compensates for the intensity of the background lighting.
23. The apparatus of claim 14 wherein the wavelength of the strobable light compensates for the wavelength of the background light.
- 15 24. The apparatus of claim 14 further comprising a base.
25. The apparatus of claim 24 wherein the base is in the form of eyeglass frames with the light located near the hinge.
26. The apparatus of claim 24 wherein the base is mountable to a table.
27. The apparatus of claim 24 wherein the base is in the form of a lamp
20 stand.
28. An apparatus for inhibiting myopia development in humans comprising:
a flickering pattern of low luminance and high luminance regions;

a means of adjusting a frequency at which the pattern flickers; and
a means of adjusting a period of time over which the pattern flickers;
wherein said pattern flickers at a desired frequency for a desired time
period.

- 5 29. The apparatus of claim 28 comprising a television frequency signal
generator that delivers a television frequency signal of the flickering pattern.
30. The apparatus of claim 28 comprising a computer when programmed
to display the flickering pattern on a monitor or screen of said computer.

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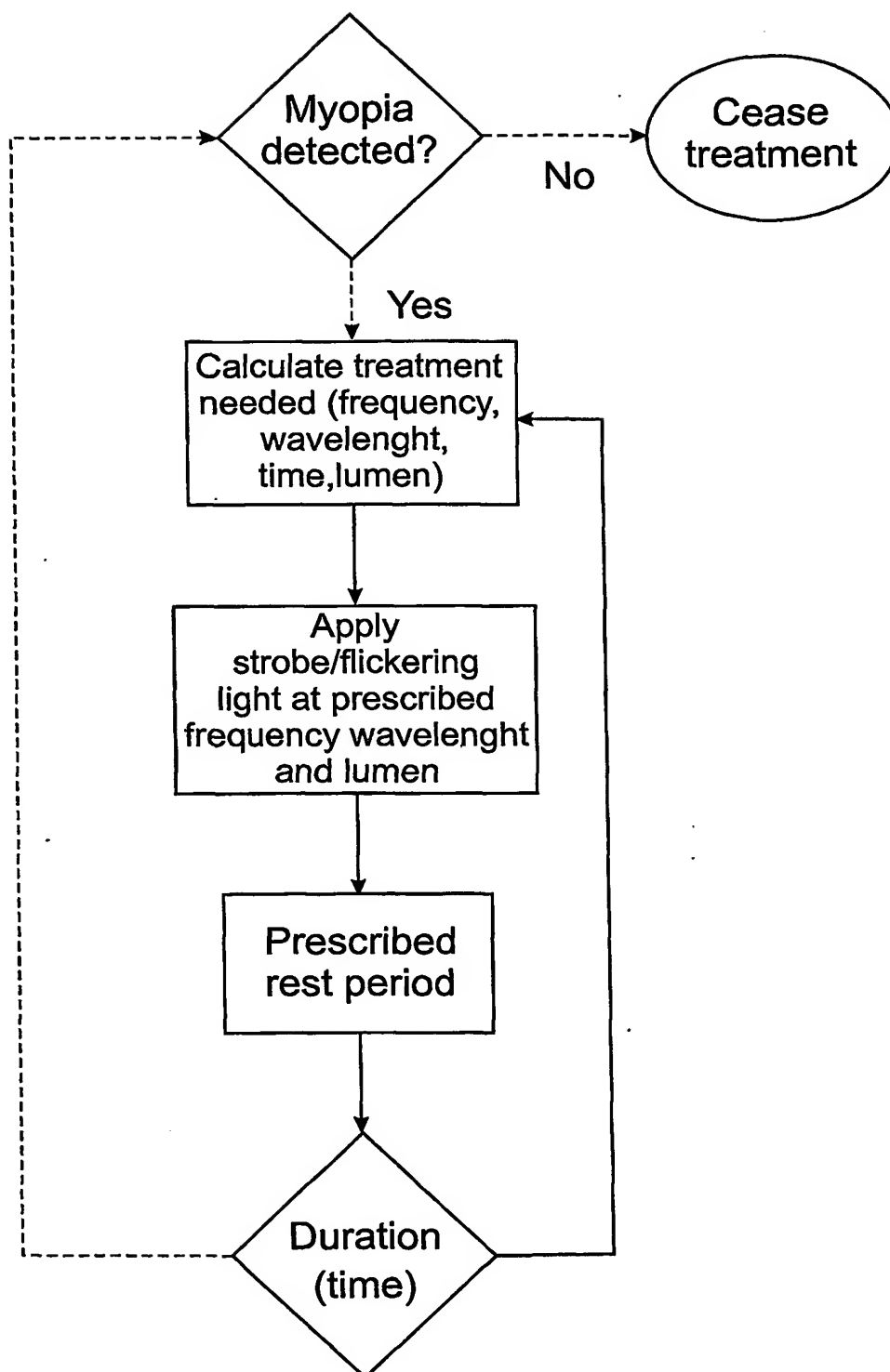


FIG. 1

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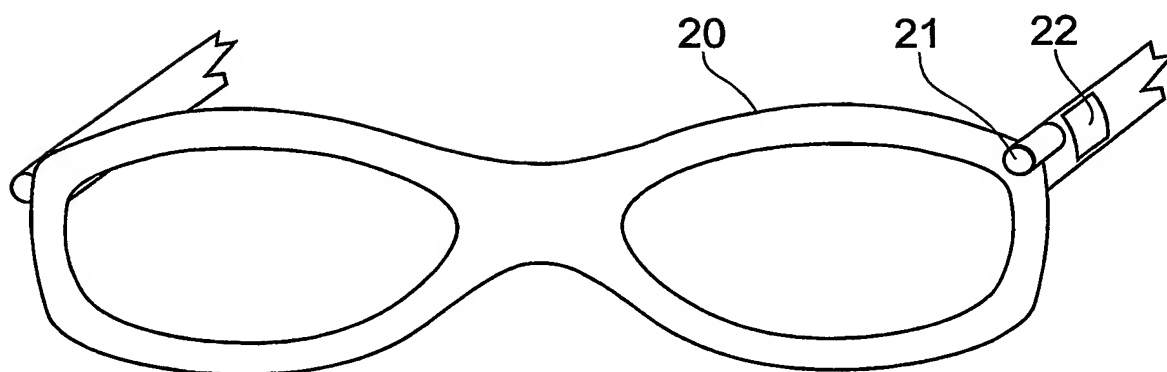


FIG. 2

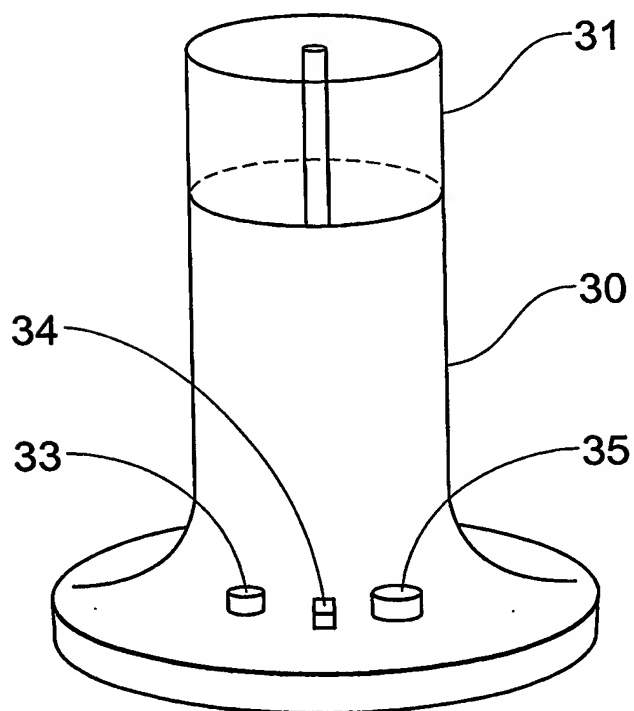


FIG. 3

INTERNATIONAL SEARCH REPORT

 International application No.
PCT/AU2003/001527

A. CLASSIFICATION OF SUBJECT MATTER		
Int. Cl. ⁷ : A61F 9/00		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols)		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) DWPI & keywords (myopia, strobe and similar terms); USPTO and similar keywords; Espace and keywords (myopia, light)		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 1997/000653 A1 (TETERINA T P) 9 January 1997 See English abstract	1,2,4-6,12,14,16-19,24 3
Y	Derwent Abstract Accession No. 2000-672993/66, Class P32;S05,	
X	CN 1260162 A (YU P) 19 July 2000	
Y	See English abstract	1,2,14,16,17,28,30 3
	Derwent Abstract Accession No. 95-300856/39, Class S05, RU 2029488 C1 (TITOV P A) 27 February 1995	
X	See English abstract	1,2,14,16,24,27 3
Y		
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 25 February 2004		Date of mailing of the international search report - 3 MAR 2004
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929		Authorized officer STEPHEN CLARK Telephone No : (02) 6283 2781

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2003/001527

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	Derwent Abstract Accession No. E3854 K/13, Class P32, SU 931185 A (MOSC EYE DISEASE) 1 June 1982 See English abstract	1,2,14,16 3
X Y	US 5382987 A (SPERLING) 17 January 1995 See summary at columns 2-3	1,28-30 3
X Y	GB 2196442 A (ANDERSON) 27 April 1988 See whole document	14,16,24,25 3
Y	Derwent Abstract Accession No. 92-006078/01, Class P31, SU 1627112 A (EYE MICROSURGERY) 15 February 1991 See English abstract for testing for myopia	3
A	US 5520543 A (MITUI) 28 May 1996 See whole document	1,28-30
A	US 4057054 A (GIANNONE) 8 November 1977 See whole document	1-30
		o

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2003/001527**Box I** Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos :
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos :
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos :
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box II Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Claims 1-13 and 15 relate to a method of treating myopia;

Claims 14 and 16-27 relate to a strobe light merely useful for the treatment of myopia, but otherwise a normal strobe;

Claims 28-30 relate to a flickering pattern, again only useful for the treatment.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU2003/001527

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report			Patent Family Member		
WO	1997/000653	NONE			
CN	1260162	NONE			
RU	2029488	NONE			
SU	931185	NONE			
US	5382987	AU	38103/93	US	5506633
GB	2196442	NONE			WO 1993/024047
SU	1627112	NONE			
US	5520543	NONE			
US	4057054	NONE			

END OF ANNEX